

Notice of Allowability

Application No.

10/826,523

Examiner

Jennifer Dunston

Applicant(s)

FRASER ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 9/30/2005.
2. ☒ The allowed claim(s) is/are 9-13 and 16-19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☒ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input checked="" type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Denise Mayfield on 10/21/2005.

The application has been amended as follows:

In the specification:

At page 1, paragraph [01], – now US Patent No. 6,962,810, – has been inserted between “filed October 30, 2001,” and “which claims priority”.

At page 1, paragraph [01], the word “five” in the last sentence has been replaced with the word “four”.

At page 1, paragraph [01], the phrase “Attorney Docket No. UNND-0061-4” has been deleted.

Duplicate page 6 has been deleted.

In the claims:

Claim 13 has been amended to include a period at the end of the sentence.

Examiner's Comment Regarding Requirement for Deposit of Biological Material

Applicant's arguments filed 9/30/2005 have been fully considered but they are not persuasive.

With regard to claims 10 and 17, the response asserts that ITR1.1k is described in the specification at paragraph 93 and that the ITR sequence employed to prepare the ITR1.1k is provided in SEQ ID NO: 40. Even though SEQ ID NO: 40 contains sequences used in the preparation of ITR1.1k, paragraph 93 of the present specification does not provide sufficient detail to enable one to make the ITR1.1k cassette. Additional detail regarding how to make ITR1.1k can be found in paragraphs 97 and 109. Paragraph 97 indicates that ITR1.1k is an EcoRV/DraI fragment of pIAO-p/L-589 bp. Although pIO-p/L-589 bp is prepared from pIAO-p/L (SEQ ID NO: 57) sufficient detail is not provided to enable one to prepare pIAO-p/L-589 bp. Although Li et al (2001b) teach the pIAO-p/L-589 bp, it is not clear that the plasmid is readily available.

Regarding claim 12, the response asserts that the vector designated pXL-BacII-ECFP is described at paragraphs 66-67 and 93. Although the specification teaches the PCR primers used to amplify the sequence inserted into pXL-Bac (SEQ ID NO: 41), it is not clear which nucleic acid molecule taught by Horn and Wimmer (2000) was used as a template for the PCR reaction and if the nucleic acid molecule used as a template is readily available.

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Regarding claim 13, the response asserts that the vector designated pBSII-ITR1.1k-ECFP is described in the specification at paragraph 97 and is depicted in Figure 24. Although the specification teaches the insertion of an EcoRV/DraI fragment of pIAO-p/L-589 bp into the EcoRV site of pBSII-3xP3-ECFP (Horn and Wimmer (2000)), it is not clear that the starting materials required for this process are readily available.

Therefore, claims 10, 12, 13 and 17 are in conditions for allowance except for a required deposit. The deposit of vectors pXL-BACII-ECFP and pBSII-ITR1.1k-ECFP would be sufficient to satisfy the deposit requirement. Please see the attached suggestions for deposit of biological material. The Office has received a written assurance that an acceptable deposit will be made (response page 5, 5th full paragraph). Failure to make the needed deposit in accordance with this requirement will be considered a failure to prosecute the application under 35 U.S.C. 133 and result in abandonment of the application.

Once the deposit has been made, information regarding the deposit, such as the name and address of the depository, the accession number and the date of the deposit, that is to be added to the specification must be added by means of filing an amendment under the provisions of 37 CFR 1.312. Such an amendment must be filed before or with the payment of the issue fee. Therefore, applicants need to make any necessary deposit of biological material well prior to payment of the issue fee such that the accession number is received with sufficient time remaining to amend the specification as required by 37 CFR 1.809(d) on or before the date the issue fee payment is paid. See 37 CFR 1.809(e).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, <http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

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TERRY MCKELVEY
PRIMARY EXAMINER

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SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.